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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,981	12/13/2000	Steven Kurt Spaderna	15966-620 (Cura 120)	5695
30623	7590	04/28/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,981

Applicant(s)

SPADERNA ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claims 1 to 43 are pending in the instant application.

Claims 1 to 43 are objected to as reciting an improper Markush Group. M.P.E.P.

803.02 states that:

“Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish* , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi* , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

The eight different amino acid sequences recited in the instant claims do not reflect a common inventive concept because proteins comprising those different sequences do not share a common utility that is based upon a distinguishing feature or combination of features lacking from the prior art.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I to VIII. Claims 1 to 4, 29, 32 and 35, only in so far as they relate to an isolated polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 530, subclass 350. Invention I consists of claims 1 to 4, 29, 32 and 35 only in so far as they relate to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:2. Invention VIII consists of claims 1 to 4, 29, 32 and 35 only in so far as they relate to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:16.

IX to XVI. Claims 5 to 14, 30, 33 and 36, only in so far as they relate to an isolated polynucleotide encoding one of the eight different amino acid sequences recited therein, classified in class 435, subclass 69.1.

XVII to XXIV Claims 15 to 17, 31, 34 and 37, only in so far as they relate to an antibody that binds to a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 424, subclass 143.1.

XXV to XXXII. Claims 18 and 40, only in so far as they relate to an immunoassay employing an antibody that binds to a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 436, subclass 501.

XXXIII to XL. Claims 19 and 41, only in so far as they relate to a method of detecting a polynucleotide encoding one of the eight different amino acid sequences recited therein in a sample, classified in class 435, subclass 6.

XLI to XLVIII. Claims 20 and 21, only in so far as they relate to a ligand-specific binding assay employing a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 435, subclass 7.21.

XLIX to LVI. Claim 22, only in so far as it relates to a method of treatment by administering a compound of unspecified constitution that binds to a polypeptide comprising one of the eight different amino acid sequences recited therein, classification undeterminable.

LVII to LXIV. Claims 23, 24 and 42, only in so far as they relate to a method of treatment by administering a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 514, subclass 2.

LXV to LXXII. Claims 25 and 26, only in so far as they relate to a method of treatment by administering a polynucleotide encoding a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 514, subclass 44.

LXXIII to LXXX. Claims 27, 28 and 43, only in so far as they relate to a method of treatment by administering an antibody that binds to a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 424, subclass 143.1.

LXXXI to LXXXVIII. Claims 38 and 39, only in so far as they relate to a ligand-specific binding assay employing a transgenic animal containing a recombinant nucleic acid encoding a polypeptide comprising one of the eight different amino acid sequences recited therein, classified in class 800, subclass 3.

The inventions are distinct, each from the other because:

The eight polypeptides of inventions I to VIII, the eight nucleic acids of inventions IX to XVI, the eight antibodies of inventions XVII to XXIV, the eight compounds of unspecified constitution employed in the methods of inventions XLIX to LVI and the eight transgenic animals employed in the methods of inventions LXXXI to LXXXVIII are

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forty different compounds and compositions each of which can be made and used without the others. They are shown to be distinct because they lack a common utility that is based upon a common feature or combination of features lacking from the prior art.

The polypeptides of inventions I to VIII are related to the assays of inventions XLI to XLVIII and the methods of treatment that are inventions LVII to LXIV as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the assays of inventions XLI to XLVIII are materially different from the methods of treatment that are inventions LVII to LXIV because they achieve different objectives by employing different steps.

The polynucleotides of inventions IX to XVI are related to the assays of inventions XXXIII to XL and the methods of treatment that are inventions LXV to LXXII as products and processes of use. The inventions are shown to be distinct because the assays of inventions IX to XVI are materially different from the methods of treatment that are inventions LXV to LXXII because they achieve different objectives by employing different steps.

The antibodies of inventions XVII to XXIV are related to the assays of inventions XXV to XXXII and the methods of treatment that are inventions LXV to LXXII as products and processes of use. The inventions are shown to be distinct because the

assays of inventions IX to XVI are materially different from the methods of treatment that are inventions LXXIII to LXXX because they achieve different objectives by employing different steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

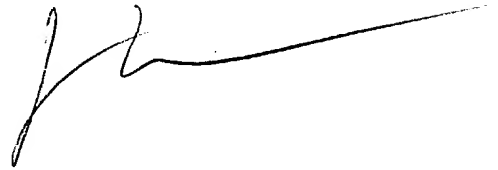
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
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